

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER 37 CFR 1.132

David C. Steinberg declares as follows:

1. I am currently President of Steinberg & Associates, Inc. a consulting corporation I founded. I have also been Vice President of Research at Hansotech, a company in the wax, oils and fats business. I also was employed at Emery Industries (now Cognis) a key manufacturer of fatty products.
2. I am considered an expert in the fields of oils, waxes and butters and consult regularly in the field to many corporations. I have also been an expert witness in the field. I have over 30 years experience in this field.
3. I am certainly one of ordinary skill in the art of products derived from natural oils.
4. I have reviewed four related applications currently pending before the United States Patent Office. These applications are:

Serial No: Filed
10/444,470 05/27/2003

Title: Guerbet Cranberry Esters as a Delivery System for Natural Antioxidants

Serial No: Filed:
10/444,471 05/27/2003

Title: Guerbet Raspberry Esters as a Delivery System for Natural Antioxidants

Serial No: Filed
10/600,251 06/23/2003

Title: Cranberry Amido Amines and Betaines as a Delivery System for Natural Antioxidants

Serial No: Filed:
10/620,899 07/17/2003

Title: Guerbet Cranberry Esters as a Delivery System for Natural Antioxidants

4. All of these patents stand rejected under 35 USC 112 because it is claimed the "R" component is not properly defined as not to be clear to one of ordinary skill in the art.
5. In order to address this issue, it must be understood that natural oils are defined by several concepts.

a. The source of the oil

The four applications are very clear on this matter:

American cranberries, *Vaccinium macrocarpon*, are native plants of open, acid peat bogs in North America. Cranberry plants are evergreen perennial vines that produce runners and upright branches with terminal flower buds.

Raspberry Oil

The oil is referred to as *Rubus idaeus* seed oil and has a CAS number of 381718-28-

b. The process of extracting.

The applications clearly state the particular patent describing the cold pressed oil U.S. patent 6,391,345 issued May 2002 describes the refining of cold pressed oils and incorporate the patent by reference.

c. The composition of the oil

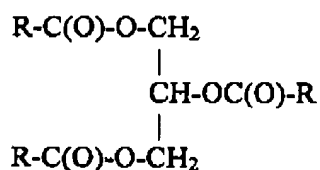
The oils processed by a particular process have salient properties. One is carbon distribution (typically C-16 to C-18 esters either saturated or mono or di unsaturated fatty acids); the other important aspect is the non-triglyceride active components present. The current applications not only distinctly claim the carbon distribution

using names known to those skilled in the art. But also gives ranges of each component, than defines all these active components.

Applicants clearly state:

A. Raspberry

[015] Cold Pressed Raspberry Oil is a triglyceride conforming to the following structure:



[016] The oil is referred to as *Rubus idaeus* seed oil and has a CAS number of 381718-28-1

The R-C(O)- group has the following composition:

<u>Component</u>	<u>% Weight</u>
18:1 oleic	10-20
18:2 linoleic	30-40
18:3 linolenic (alpha)	45-55
alpha tocopherol	46 mg/gram
Ellagic Acid	450-650 ppm

[017] Distribution by type of fatty group

<u>Component</u>	<u>% Weight</u>
Saturated	3%
Polyunsaturated content	86%
Mono unsaturated	11%

[018] The oil contains the following very critical "active" components for skin and hair care:

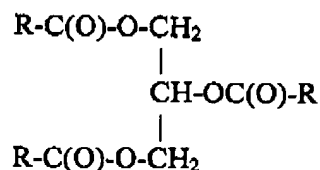
<u>Material</u>	<u>Concentration</u>
18:3 linolenic (alpha)	45-55%
alpha tocopherol	46 mg/gram
Ellagic Acid	450-650 ppm

Applicants then point out the unexpected benefit of the products derived from the oil:

[019] As can be seen, the cold pressed raspberry seed oil is a rich source of compounds having important properties when applied to hair and skin. The cold pressed raspberry oil can shield against UV-A induced damage by scattering light as well as by light spectrum absorption. The cold pressed raspberry oil has, then activity as a broad spectrum UV protectant. The raspberry oil may be used alone or in combination with other recognized conventional sunscreens. (emphasis Added)

B. Cranberry

[[015] Cold Pressed Cranberry Oil is a triglyceride conforming to the following structure:



[016] The R-C(O)- group has the following composition:

Component	% Weight
16:0 palmitic	5.0 to 6.0
18:0 stearic	1.0 to 2.0
18:1 oleic	20 to 25
18:2 linoleic	35 to 40
18:3 linolenic (alpha)	30 to 35
20:0 arachidic	0.13
20:1 gadoleic	0.20
20:5 (n-3)	0.32
22:2	1.1
Myristic	0.01
Pentadecanoic	0.02
Palmitoleic (trans)	0.13
Palmitoleic (cis)	0.08
10-heptadecanoic	0.03
Gamma linolenic	0.1 to 0.2
Nonadecanoic	0.1 to 0.2
11-transeicosenic	0.22
11, 14 eicosandienoic	0.1
11, 14, 17 eicosatrienoic	0.01
Eicosapentaenoic	0.01
Behenic	0.03
Erucic	0.02
Docosapentaenoic	0.01
Tricosanoic	0.01
Lignoceric	0.02
Nervonic	0.02

[017] The oil also contains the following very critical "active" components for skin and hair care:

Compound	mg/kg
Campesterol/brassicasterol (mg/kg)	66.0
Stigmasterol (mg/kg)	68.0
Beta-sitosterol (mg/kg)	1319.0
Phosphatidylinositol (mg/kg)	9.9
Phosphatidylcholine (mg/kg)	202.0
Alpha-tocopherol (mg/kg)	341.0
Gamma-tocopherol (mg/kg)	110.0

[018] When the oil is exposed to conventional extraction procedures of steam stripping and solvent extraction, the concentration of the "active" components drops to vanishingly small levels and the activity is lost.

[019] As can be seen, the cold pressed cranberry seed oil is a rich source of compounds having important properties when applied to hair and skin. Stigmasterol is an anti-stiffness factor. Beta-sitosterol has use as an antihyperlipoproteinemic agent. One or more of the campesterol, stigmasterol and beta-sitosterol has inflammatory and may be useful in the treatment of gingivitis, rash, eczema, and other skin lesions. It is also believed that these compounds found in cranberry seed oil have activity as sunscreen agents, since some of the compounds present in cranberry oil have absorbance in the UV-B range. This is this range that causes the greatest cellular damage to humans. The cold pressed cranberry oil can shield against UV-A induced damage by scattering light as well as by light spectrum absorption. The cold pressed cranberry oil has, then activity as a

broad spectrum UV protectant. The cranberry oil may be used alone or in combination with other recognized conventional sunscreens.

6. The current applications then go on to claim:

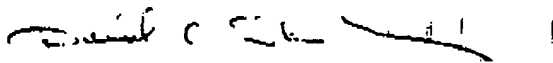
R is derived from cold pressed cranberry or raspberry oil.

This term links all attributes of the oil together and specifies the oil from which they are derived. This is the best most effective way to specify all of the properties described above using the antecedent basis provided throughout the applications.

7. There is simply no better way known to this expert to get all of the elements as well defined as in the current application. I clearly know all attributes of the product claimed.

In conclusion, in my expert opinion, the Applicant language saying R is derived from cold pressed oil has proper antecedent basis and is abundantly clear to one of ordinary skill in the art.

Further declarant sayeth not.



David C. Steinberg
Declarant
April 16, 2006